

REMARKS

Claims 36 to 65 are pending in this patent application and stand rejected. Claims 45 and 60 have been amended to replace the transitional term “includes” with “consists essentially of.”

Applicants acknowledge with appreciation the indication in the Office Action dated August 7, 2006 that the rejections over the Duan and Clark references have been withdrawn.

The Office Action includes a new rejection of claims 36, 37, 39 to 48, 50 to 52, 54 to 63 and 65 under 35 U.S.C. § 102(b) over WO 90/09781 (“Felt”). All of the pending claims were also rejected under 35 U.S.C. § 103 over Felt in combination with Barnes et al., U.S. Patent No. 5,894,964 (“Barnes”). Applicants respectfully traverse these rejections.

The Office Action acknowledges that Felt requires a solvent and surfactant, which would be excluded by the “consisting essentially of” transitional phrase used in the instant claims, if these elements affect the basic and novel characteristics of the claimed compositions. However, the Action contends that it is Applicants’ burden to make such a showing.

Applicants’ response is that evidence establishing that the term “consisting essentially of” is sufficient to patentably distinguish the claimed subject matter from the compositions described in Felt may be found in the reexamination file history of Adjei et al., U.S. Patent No. 6,136,294 (“Adjei”), from which the instant claims were copied. During reexamination of claims in Adjei that were substantially the same as those being prosecuted in the instant application (except for their utilization of the transitional term “comprises”) the examiner entered a rejection for alleged anticipation in view of Felt. In response, the patentee replaced the term “comprises” with the transitional phrase “consisting essentially of.” The examiner allowed the amended claims, stating that “the prior art does not teach or suggest a medicinal aerosol formulation which consists essentially of a therapeutically effective amount of a particulate medicament, a propellant and a stabilizer selected from an amino acid . . . whereby said medicament and said stabilizer are different.” Statement of Reasons For Patentability And/Or Confirmation in Reexamination No. 90/006,032, dated May 16, 2002, signed by Examiners Haghighatian, Hartley and Dees.

Applicants respectfully submit that if use of the transitional phrase “consisting essentially of” was sufficient to confer patentability over Felt during reexamination of Adjei, the same must be sufficient to confer patentability to the instant claims, which are substantially identical. Moreover, the instant application teaches that surfactants, such as oleic acid (utilized in the cited example from Felt), may impart a bitter taste and thereby adversely affect use of inhalers in which such surfactants are used. *See, e.g.*, page 2, lines 20 to 22.

With regard to the rejection of the remaining claims under Section 103 over Felt in combination with Barnes, since these rejections still depend on Felt, with Barnes being relied on solely for its teaching of suitable propellants, Applicants respectfully submit that the claims are distinguishable from the combined teachings of Felt and Barnes for the same reasons that they are distinguishable from the teaching of Felt alone.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the pending rejections, and an acknowledgement that the claims define allowable subject matter.

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